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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/685,338	07/23/1996	LIXIAO WANG	S63.2-5902	3558

490 7590 02/04/2004

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

RODRIGUEZ, CRIS LOIREN

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/685,338

Applicant(s)

WANG ET AL.

Examiner

Cris L. Rodriguez

Art Unit

3763

-- Th MAILING DATE of this communication app ars on the cov r she t with the corresp nd nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43 and 48-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43 and 48-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: reference to application Serial No. 08/611,644 now US Patent 5,805,600 might be incorrect. Please revise.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 43, and 48-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as filed has no support for the claimed subject matter "the balloon being a presterilized balloon", and "the balloon being mounted on a catheter" in claim 48.

4. **Please note that claims 55-66 contain subject matter that was already decided by the Board of Appeals, with the exception of the new subject matter. If Applicant removes the subject matter from those claims, it may constitute proper ground for *Res judicata* rejection.**

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton et al (US 5,797,877) in view of Anderson et al (US 5,500,180).

Hamilton teaches a double layer balloon made from at least two concentric layers of different thermoplastic polymers (col. 4, lines 6-29, see also disclosure for more details). Hamilton also teaches single layer balloons. The inclusion of a thermoplastic material in such balloons is to give a superior balance to the balloon properties such as a lower balloon resistance to inflation and deflation pressure (burst strength), and the ability to maintain a pre-selected diameter or hoop strength (radial tensile strength). Hamilton specifies that by varying the fabrication method and/or layer or blend materials and ratios, the balance of structural and surface properties of the balloon may be precisely tailored for a specific procedure. However, Hamilton fails to specifically disclose the balloon being presterilized, a burst pressure of at least 9 atmospheres, a diameter at 3 atmospheres of about 2 mm or more and an average compliance over the range of from 3 atmospheres to burst of at least 3% per atmosphere.

Anderson teaches a thermoplastic polymeric material balloon having the following parameters such as:

- 1) operational pressures that the balloon can be safely inflated without bursting of at least 12 atm (see Examples 3 and 4),
- 2) a nominal diameter of 3 mm at a certain inflation pressure, and
- 3) a diameter growth disclosed at column 4 lines 59-65 over a range of 3-12 atm.

Anderson also teaches, in column 3 line 32-column 4 line 65,

- 4) an average compliance (distensibility) to burst the balloon, and in column 6 lines 5-23 discloses average compliance for the balloon of about 5 to 20%, and
- 5) burst pressures of at least 9 atm (see Examples 3 and 4).

Further, Anderson teaches that all these balloon characteristics depend from the material construction and the wall thickness of the balloon that are controllable during the process of making the balloon, and that the balloon is sterilized prior to be inserted in the body. Given the teachings, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide Hamilton's single or double balloons with the Anderson's balloon material parameters and characteristics, since such parameters are deemed matters of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimal results of the claimed balloon, and to sterilize the balloon as taught old and well known by Anderson.

7. Claims 55-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al.

With respect to claims 55-59, Anderson teaches the balloon as claimed having the following parameters such as : 1) operational pressures which the balloon can be

safely inflated without bursting of at least 12 atm (see examples 3 and 4), 2)a nominal diameter of 3 mm at a certain inflation pressure, and 3)a diameter growth disclosed at column 4 lines 59-65 over a range of 3-12 atm. With respect to claims 60-64, Anderson teaches in columns 3 line 32 – column 4 line 65), 4)an average compliance (distensibility) to burst the balloon, and in column 6 lines 5-23 discloses average compliance for the balloon of about 5 to 20%, and 5)burst pressures of at least 9 atm (see Examples 3 and 4). Further, Anderson teaches that all these balloon characteristics depend from the material construction and the wall thickness of the balloon which are controllable during the process of making the balloon. However, Anderson fails to disclose all the varying parameters of the 1)operational pressure, 2)nominal diameter at an inflation pressure of 3 atm, 3)diameter growth, and 4)average compliance as claimed. Such parameters are deemed to have been an obvious design choice, obvious to and well within the level of skill of the ordinary artisan achieved through routine experimentation in determining similar optimal results for the claimed balloons.

8. Claims 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in view of Cohen et al (US 5,167,239).

Anderson discloses the invention substantially as claimed. However, Anderson fails to disclose a method of treating a gastrointestinal lesion having the steps as claimed.

Cohen teaches an anchorable guidewire for treating a gastrointestinal lesion having the steps as claimed (see col. 42-55 and throughout the specification). It would

have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the guidewire of Cohen with Anderson's catheter and treat a gastrointestinal lesion using the steps taught by Cohen where substituting one device for the other would have been obvious depending on Applicant's intention.

Response to Arguments

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3763

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 30, 2004



Cris L. Rodriguez
Examiner
Art Unit 3763



BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700